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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,198	07/19/2000	Hai Yan	MBHB00-422	2259

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08/21/2003

Kevin E Noonan
McDonnell Boehnen Hubert & Berghoff
300 South Wacker Drive
Suite 3200
Chicago, IL 60606

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/21/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/619,198

Applicant(s)
Yan et al

Examiner
Robert C. Hayes, Ph.D.

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 24, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 12, and 13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 12, and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 14
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/03 has been entered.

2. The amendment filed 4/24/03 has been entered.

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

4. The rejection of claims 6 and 11 under 35 U.S.C. 102(b) as being anticipated by Salton et al. (1991) is withdrawn solely due to the amendment of the claims, and because Salton et al. states on page 994 that their rat NGF33.1 cDNA and VGF cDNA correspond to the same gene. However, it should be noted that amending the claims to obviate the new matter rejection below may necessitate re-instatement of this rejection, or a corresponding rejection under 103.

Art Unit:

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicants' arguments filed 4/24/03 have been fully considered but they are not deemed to be persuasive.

7. The amendment filed 4/24/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The new amendments to the description of Figures 2 & 3 do not appear to have proper support within the specification; thereby, constituting new matter. Note also that the recitation "calculated at 1:100 to 2x serial dilution" is a new amendment to Figures 2 & 3 within the specification, and therefore, should have been underlined.

In contrast, the amendment to the description of Figure 1 does appear to inherently flow from the disclosure on pages 79-80 of the specification.

Applicant is required to cancel the new matter in the reply to this Office Action, or provide evidence where proper basis for this amendment to the specification existed at the time of filing the instant application.

Art Unit:

8. Claims 6-9 & 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application is apparent for the new claim limitation of "an amino acid sequence *derived from a non-VGF gene* fused to the amino acid sequence of SEQ ID NO:7". In contrast, as discussed during the interview of 3/04/03, only specific fusion polypeptides are contemplated within the specification (e.g., VGF-IgG1-Fc fusion polypeptides as on page 81; and specific "tag" sequences for "purification of a VGF polypeptide" as described on pages 39-40 of the specification). In other words, no broader scope sequences "derived from a non-VGF gene fused" are contemplated within the instant specification, nor are such negative limitations contemplated; thereby, constituting new matter.

9. Claims 6-9 & 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes "fusion polypeptides" on pages 20-21 & 39-40 of the specification. Although specific VGF fusion proteins are described, in which VGF polypeptides

Art Unit:

are fused to "tag" sequences to aid in "purification" of VGF polypeptides, or which are fused to the "Fc region" of IgG molecules in order to "exhibit a substantially greater half-life *in vivo*" or to "reduce aggregation", not a single "gene" nor "non-VGF gene" (e.g., as it relates to unknown and undescribed promoters, 5'- or 3'- flanking regions, enhancers or introns, etc.) is described within the instant specification. Nor are any amino acid sequences "derived from a non-VGF gene" described. Thus, one of ordinary skill in the art could not reasonably visualize what constitutes such generic sequences that make up such generic "fusion polypeptides". *In arguendo*, although a subgenus of VGF fusion polypeptides are described, where the fusion protein is constructed to aid in "purification" of VGF polypeptides, or to "exhibit a substantially greater half-life *in vivo*", the widely-variable genus of "amino acid sequences derived from a non-VGF gene fused to ... SEQ ID NO:7" is not reasonably described; thereby, not meeting the written description requirements under 35 U.S.C. 112, first paragraph.

Applicant is directed toward the Revised Interim Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999. See especially Examples 6, 13 & 17.

10. Claims 6-9 & 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit:

It is confusing how "a non-VGF gene [can be] fused to the amino acid sequence of SEQ ID NO:7" since nucleotide sequences and amino acid sequences normally are not "fused" to each other. In other words, nucleotide sequences are "derived from a... gene"; not "amino acid sequences", as currently claimed; thereby, making the claims ambiguous.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.

August 19, 2003

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